IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF DELAWARE

PURDUE PHARMA L.P., PURDUE PHARMACEUTICALS L.P., THE P.F. LABORATORIES, INC., and RHODES TECHNOLOGIES,	)	
Plaintiffs,	)	C.A. No. _____
v.	)	
ABHAI, LLC and KVK-TECH, INC.,	)	
Defendants.	)	

COMPLAINT

Plaintiffs Purdue Pharma L.P., Purdue Pharmaceuticals L.P., The P.F. Laboratories, Inc. (collectively, "Purdue"), and Rhodes Technologies ("Rhodes") (collectively, "Plaintiffs"), for their Complaint against Defendants Abhai, LLC ("Abhai") and KVK-TECH, Inc. ("KVK") (collectively, "Defendants"), aver as follows:

NATURE OF THE ACTION

1. This is an action for patent infringement arising under the patent laws of the United States, Title 35, United States Code, for infringement of United States Patent Nos. 9,492,389 ("the '389 patent"); 9,492,391 ("the '391 patent"); 9,492,392 ("the '392 patent"); 9,492,393 ("the '393 patent") and 9,522,919 ("the '919 patent") (collectively, "the patents-in-suit"). This action relates to Abbreviated New Drug Application ("ANDA") No. 207493 ("Defendants' ANDA") submitted upon information and belief in the name of Defendants to the United States Food and Drug Administration ("FDA").

2. Plaintiffs seek judgment that Defendants have infringed the '389, '391, '392, '393, and '919 patents, which are listed in the FDA *Approved Drug Products With*

Therapeutic Equivalence Evaluations ("Orange Book") as covering Purdue's OxyContin® (oxycodone hydrochloride) ("OxyContin®"), an extended-release pain medication. Defendants have infringed the Orange Book patents under 35 U.S.C. § 271(e)(2)(A) by filing ANDA No. 207493, submitted in the name of Defendants to the FDA. Defendants' ANDA seeks approval to market a generic version of Purdue's OxyContin®, which is the subject of approved New Drug Application ("NDA") No. 022272, in the 10 mg, 15 mg, 20 mg, 30 mg, 40 mg, 60 mg, and 80 mg dosage strengths ("Defendants' ANDA Products").

THE PARTIES

3. Plaintiff Purdue Pharma L.P. ("Purdue Pharma") is a limited partnership organized and existing under the laws of the State of Delaware, having a place of business at One Stamford Forum, 201 Tresser Boulevard, Stamford, Connecticut 06901-3431. Purdue Pharma is an owner of the '389, '391, '392, '393, and '919 patents, identified in paragraphs 19-23 below. Purdue Pharma is also the holder of approved NDA No. 022272 for OxyContin®, indicated for pain severe enough to require daily, around-the-clock, long-term opioid treatment and for which alternative treatment options are inadequate. Purdue Pharma sells OxyContin® in the United States.

4. Plaintiff Purdue Pharmaceuticals L.P. ("Purdue Pharmaceuticals") is a limited partnership organized and existing under the laws of the State of Delaware, having a place of business at 4701 Purdue Drive, Wilson, NC 27893. Purdue Pharmaceuticals is an owner of the '389, '391, '392, '393, and '919 patents, identified in paragraphs 19-23 below.

5. Plaintiff The P.F. Laboratories, Inc. ("P.F. Labs") is a corporation organized and existing under the laws of the State of New Jersey, having a place of business at One Stamford Forum, Stamford, CT 06901. P.F. Labs is an owner of the '919 patent, identified in paragraph 23 below.

6. Plaintiff Rhodes Technologies ("Rhodes") is a general partnership organized and existing under the laws of the State of Delaware, having a place of business at 498 Washington Street, Coventry, RI 02816. Rhodes is an owner of the '919 patent, identified in paragraph 23 below, and is involved in the manufacture of the active pharmaceutical ingredient ("API") used in OxyContin®.

7. On information and belief, Defendant Abhai is a limited liability company organized and existing under the laws of the State of Florida, having a principal place of business at 194 Inlet Drive, St. Augustine, FL 32080.

8. On information and belief, Defendant KVK is a corporation organized and existing under the laws of the Commonwealth of Pennsylvania, having a principal place of business at 110 Terry Drive, Suite 200, Newtown, PA 18940.

SUBJECT MATTER JURISDICTION AND VENUE

9. This action arises under the patent laws of the United States, including 35 U.S.C. § 271 and the Declaratory Judgment Act, 28 U.S.C. §§ 2201 and 2202.

10. This Court has subject matter jurisdiction pursuant to 28 U.S.C. §§ 1331 and 1338(a).

11. Venue is proper in this Court pursuant to 28 U.S.C. §§ 1391(b), 1391(c), and 1400(b), because Defendants have committed an act of patent infringement in this Judicial District.

PERSONAL JURISDICTION

12. This Court has personal jurisdiction over each of the Defendants by virtue of, *inter alia,* their systematic and continuous contacts with Delaware and contacts with Delaware in connection with the submission of Defendants' ANDA, as set forth below.

13. On information and belief, Defendant KVK holds current and valid "Distributor/Manufacturer CSR" and "Pharmacy-Wholesale" licenses from the Delaware Board of Pharmacy.

14. On information and belief, Defendants are in the business of preparing generic pharmaceuticals that they distribute in the State of Delaware and throughout the United States.

15. On information and belief, if ANDA No. 207493 is approved, the Defendants' ANDA Products would, among other things, be marketed and distributed in Delaware, and/or prescribed by physicians practicing and dispensed by pharmacies located within Delaware, all of which would have a substantial effect on Delaware.

16. On information and belief, Defendants have admitted to, consented to or have not contested, the jurisdiction of this Court, and/or have availed themselves of the rights, benefits, and privileges of this Court by asserting counterclaims in a pending District of Delaware action, *Purdue Pharma L.P. et al. v. Abhai, LLC et al.*, C.A. No. 16-25 (RGA) (SRF).

17. This Court also has personal jurisdiction over Defendants by virtue of the fact that they directed their "Notice of Paragraph IV Certification" to Plaintiffs, including Plaintiffs Purdue Pharma and Purdue Pharmaceuticals, which are limited partnerships organized and existing under the laws of the State of Delaware, and Plaintiff Rhodes, which is a general partnership organized and existing under the laws of the State of Delaware.

18. This Court further has personal jurisdiction over Defendants by virtue of the fact that Defendants have committed, or aided, abetted, contributed to, and/or participated in the commission of, the tortious act of patent infringement that has led to foreseeable harm and injury to Plaintiffs, including Plaintiffs Purdue Pharma and Purdue Pharmaceuticals, which are

limited partnerships organized and existing under the laws of the State of Delaware, and Plaintiff Rhodes, which is a general partnership organized and existing under the laws of the State of Delaware.

THE PATENTS-IN-SUIT

THE '389 PATENT

19. Purdue Pharma and Purdue Pharmaceuticals are the lawful owners of all right, title and interest in the '389 patent, titled "TAMPER RESISTANT DOSAGE FORMS," including the right to sue and to recover for past infringement thereof. The '389 patent is listed in the Orange Book as covering OxyContin®, which is the subject of approved NDA No. 022272. A copy of the '389 patent is attached hereto as Exhibit A, which was duly and legally issued on November 15, 2016, naming William H. McKenna, Richard O. Mannion, Edward P. O'Donnell, and Haiyong H. Huang as the inventors.

THE '391 PATENT

20. Purdue Pharma and Purdue Pharmaceuticals are the lawful owners of all right, title and interest in the '389 patent, titled "TAMPER RESISTANT DOSAGE FORMS," including the right to sue and to recover for past infringement thereof. The '391 patent is listed in the Orange Book as covering OxyContin®, which is the subject of approved NDA No. 022272. A copy of the '391 patent is attached hereto as Exhibit B, which was duly and legally issued on November 15, 2016, naming William H. McKenna, Richard O. Mannion, Edward P. O'Donnell, and Haiyong H. Huang as the inventors.

THE '392 PATENT

21. Purdue Pharma and Purdue Pharmaceuticals are the lawful owners of all right, title and interest in the '392 patent, titled "TAMPER RESISTANT DOSAGE FORMS," including the right to sue and to recover for past infringement thereof. The '392 patent is listed

in the Orange Book as covering OxyContin®, which is the subject of approved NDA No. 022272. A copy of the '392 patent is attached hereto as Exhibit C, which was duly and legally issued on November 15, 2016, naming William H. McKenna, Richard O. Mannion, Edward P. O'Donnell, and Haiyong H. Huang as the inventors.

THE '393 PATENT

22. Purdue Pharma and Purdue Pharmaceuticals are the lawful owners of all right, title and interest in the '393 patent, titled "TAMPER RESISTANT DOSAGE FORMS," including the right to sue and to recover for past infringement thereof. The '393 patent is listed in the Orange Book as covering OxyContin®, which is the subject of approved NDA No. 022272. A copy of the '393 patent is attached hereto as Exhibit D, which was duly and legally issued on November 15, 2016, naming William H. McKenna, Richard O. Mannion, Edward P. O'Donnell, and Haiyong H. Huang as the inventors.

THE '919 PATENT

23. Purdue and Rhodes are the lawful owners of all right, title and interest in the '919 patent, entitled "OXYCODONE COMPOSITIONS," including all right to sue and to recover for past infringement thereof, which patent is listed in the FDA's Orange Book as covering OxyContin®, which is the subject of approved NDA No. 022272. A copy of the '919 patent is attached hereto as Exhibit E, which was duly and legally issued on December 20, 2016, naming Robert Chapman, Lonn S. Rider, Qi Hong, Donald Kyle, and Robert Kupper as the inventors.

DEFENDANTS' ANDA

24. On information and belief, on or before December 7, 2015, Defendants filed Defendants' ANDA in the name of Defendants with the FDA, under § 505(j) of the Federal

Food, Drug, and Cosmetic Act (21 U.S.C. § 355(j)), seeking approval to engage in the commercial manufacture, use, sale, offer for sale, or importation of Defendants' ANDA Products, generic products based on the Reference Listed Drug OxyContin®, which is the subject of approved NDA No. 022272.

25. On information and belief, Defendants subsequently submitted in their ANDA a "Paragraph IV" certification under 21 U.S.C. § 355(j)(2)(A)(vii)(IV) alleging that certain patents, listed in the Orange Book as covering OxyContin®, which is the subject of approved NDA No. 022272, are "invalid, unenforceable, and/or will not be infringed by the commercial manufacture, use, offer for sale, sale or importation of" the drug products described in Defendants' ANDA.

26. In a letter dated December 7, 2015, addressed to Plaintiffs and received by Purdue Pharma on or about December 8, 2015, Defendants provided what purports to be a "Notice of Paragraph IV Certification" with respect to Defendants' ANDA and Defendants' ANDA Products, and certain Orange Book patents, under § 505(j)(2)(B)(iv) of the Federal Food, Drug, and Cosmetic Act ("Notice Letter").

27. Defendants' submission of Defendants' ANDA was an act of infringement of said Orange Book patents under the United States Patent Law, 35 U.S.C. § 271(e)(2)(A).

28. Plaintiffs commenced a patent infringement action within the 45-day period after receiving the Notice Letter as described in 21 U.S.C. § 355(j)(5)(B)(iii), *Purdue Pharma L.P. et al. v. Abhai, LLC et al.*, C.A. No. 16-25 (RGA) (SRF) (D. Del.).

29. While the above-captioned action was pending, the patents-in-suit were issued and listed in the Orange Book as covering OxyContin®.

30. Defendants' submission of Defendants' ANDA was also an act of infringement of the patents-in-suit under the United States Patent Law, 35 U.S.C. § 271(e)(2)(A). *See, e.g.*, *Research Found. of State Univ. of N.Y. v. Mylan Pharm. Inc.*, C.A. No. 09-184-LPS, 2012 WL 1901267, at *1 (D. Del. May 25, 2012) ("A party may bring suit on patents listed in the Orange Book after the filing date of an ANDA.").

FIRST CLAIM FOR RELIEF
(PATENT INFRINGEMENT OF U.S. PATENT NO. 9,492,389)

31. Purdue Pharma and Purdue Pharmaceuticals incorporate by reference and reallege paragraphs 1 through 30 above as though fully restated herein.

32. Pursuant to 35 U.S.C. § 271(e)(2), Defendants' submission of ANDA No. 207493 to the FDA seeking approval of Defendants' ANDA Products was an act of infringement of the '389 patent by Defendants.

33. Defendants' ANDA Products, or the use or manufacture thereof, are covered by one or more claims of the '389 patent, including but not limited to independent claim 1, which recites, *inter alia*, a cured shaped pharmaceutical tablet comprising at least a first compression shaped and then air cured matrix, wherein said curing is without compression, by heated air having a temperature of at least about 62° C for a duration of at least about 5 minutes, said matrix comprising oxycodone or a pharmaceutically acceptable salt thereof in combination with at least one high molecular weight polyethylene oxide having an approximate molecular weight selected from the group consisting of 4,000,000, 7,000,000, and a combination thereof, and various claims dependent therefrom.

34. If approved by the FDA, Defendants' commercial manufacture, use, importation, sale, and/or offer for sale of Defendants' ANDA Products will infringe, contribute

to the infringement of, and/or induce the infringement of one or more claims of the '389 patent under 35 U.S.C. § 271(a)-(c).

35. Defendants' ANDA Products constitute a material part of the inventions covered by the claims of the '389 patent.

36. Upon information and belief, Defendants have been aware of the existence of the '389 patent, and have no reasonable basis for believing that Defendants' ANDA Products will not infringe the '389 patent, thus rendering the case "exceptional," as that term is used in 35 U.S.C. § 285.

37. Unless Defendants are enjoined by the Court, Purdue Pharma and Purdue Pharmaceuticals will be substantially and irreparably harmed by Defendants' infringement of the '389 patent. Purdue Pharma and Purdue Pharmaceuticals do not have an adequate remedy at law.

SECOND CLAIM FOR RELIEF
(PATENT INFRINGEMENT OF U.S. PATENT NO. 9,492,391)

38. Purdue Pharma and Purdue Pharmaceuticals incorporate by reference and reallege paragraphs 1 through 30 above as though fully restated herein.

39. Pursuant to 35 U.S.C. § 271(e)(2), Defendants' submission of ANDA No. 207493 to the FDA seeking approval of Defendants' ANDA Products was an act of infringement of the '391 patent by Defendants.

40. Defendants' ANDA Products, or the use thereof, are covered by one or more claims of the '391 patent, including but not limited to independent claim 1, which recites *inter alia*, a method of treating pain comprising administering to a patient in need thereof a pharmaceutical tablet comprising at least a first compression shaped and then air cured matrix, wherein said curing is without compression by heated air having a temperature of at least about

62° C for a duration of at least about 5 minutes, said matrix comprising oxycodone or a pharmaceutically acceptable salt thereof in combination with at least one high molecular weight polyethylene oxide having, based on rheological measurements, an approximate molecular weight selected from the group consisting of 4,000,000, 7,000,000, and a combination thereof, and various claims dependent therefrom.

41. If approved by the FDA, Defendants' commercial manufacture, use, importation, sale, and/or offer for sale of Defendants' ANDA Products will infringe, contribute to the infringement of, and/or induce the infringement of one or more claims of the '391 patent under 35 U.S.C. § 271(a)-(c).

42. Defendants' ANDA Products constitute a material part of the inventions covered by the claims of the '391 patent.

43. On information and belief, Defendants know that Defendants' ANDA Products are especially made or especially adapted for use in the infringement of one or more claims of the '391 patent.

44. On information and belief, Defendants have had and continue to have knowledge that there is no substantial non-infringing use for Defendants' ANDA Products.

45. The administration of Defendants' ANDA Products by any Healthcare Providers and patients, for the treatment of pain, will directly infringe one or more claims of the '391 patent.

46. Defendants' proposed label for Defendants' ANDA Products will explicitly instruct Healthcare Providers and patients to use Defendants' ANDA Products in a manner that will directly infringe one or more claims of the '391 patent, including but not limited to independent claim 1, which recites *inter alia*, a method of treating pain comprising

administering to a patient in need thereof a pharmaceutical tablet comprising at least a first compression shaped and then air cured matrix, wherein said curing is without compression by heated air having a temperature of at least about 62° C for a duration of at least about 5 minutes, said matrix comprising oxycodone or a pharmaceutically acceptable salt thereof in combination with at least one high molecular weight polyethylene oxide having, based on rheological measurements, an approximate molecular weight selected from the group consisting of 4,000,000, 7,000,000, and a combination thereof, and various claims dependent therefrom. OxyContin® is indicated for the management of pain severe enough to require daily, around-the-clock, long-term opioid treatment and for which alternative treatment options are inadequate.

47. If Defendants' ANDA Products are approved by the FDA, Defendants will actively induce others including, *e.g.*, Healthcare Providers and patients, to directly infringe one or more claims of the '391 patent. Since at least the November 15, 2016, Defendants have acted with knowledge, or at least with willful blindness of the fact, that the induced acts would constitute infringement of the '391 patent.

48. Defendants intend to cause direct infringement by others, *e.g.*, Healthcare Providers and patients.

49. If Defendants' ANDA Products are approved by the FDA, Defendants will take affirmative steps to induce infringement by, among other things, instructing Healthcare Providers and patients, through Defendants' proposed label, to use Defendants' ANDA Products in a manner that directly infringes one or more claims of the '391 patent. Thus, Defendants will aid, abet, urge, or encourage others including, *e.g.*, Healthcare Providers and patients, to directly infringe one or more claims of the '391 patent, and Defendants will affirmatively and specifically intend to cause direct infringement.

50. Upon information and belief, Defendants have been aware of the existence of the '391 patent, and have no reasonable basis for believing that Defendants' ANDA Products will not infringe the '391 patent, thus rendering the case "exceptional," as that term is used in 35 U.S.C. § 285.

51. Unless Defendants are enjoined by the Court, Purdue Pharma and Purdue Pharmaceuticals will be substantially and irreparably harmed by Defendants' infringement of the '391 patent. Purdue Pharma and Purdue Pharmaceuticals do not have an adequate remedy at law.

THIRD CLAIM FOR RELIEF
(PATENT INFRINGEMENT OF U.S. PATENT NO. 9,492,392)

52. Purdue Pharma and Purdue Pharmaceuticals incorporate by reference and reallege paragraphs 1 through 30 above as though fully restated herein.

53. Pursuant to 35 U.S.C. § 271(e)(2), Defendants' submission of ANDA No. 207493 to the FDA seeking approval of Defendants' ANDA Products was an act of infringement of the '392 patent by Defendants.

54. Defendants' ANDA Products, or the use or manufacture thereof, are covered by one or more claims of the '389 patent, including but not limited to independent claim 1, which recites, *inter alia*, a cured shaped pharmaceutical tablet comprising at least a first compression shaped and then air cured matrix, wherein said curing is without compression, by heated air having a temperature of at least about 62° C for a duration of at least about 5 minutes, said matrix comprising oxycodone or a pharmaceutically acceptable salt thereof in combination with at least one high molecular weight polyethylene oxide having an approximate molecular weight selected from the group consisting of 4,000,000, 7,000,000, and a combination thereof, and various claims dependent therefrom.

55. If approved by the FDA, Defendants' commercial manufacture, use, importation, sale, and/or offer for sale of Defendants' ANDA Products will infringe, contribute to the infringement of, and/or induce the infringement of one or more claims of the '392 patent under 35 U.S.C. § 271(a)-(c).

56. Defendants' ANDA Products constitute a material part of the inventions covered by the claims of the '392 patent.

57. Upon information and belief, Defendants have been aware of the existence of the '392 patent, and have no reasonable basis for believing that Defendants' ANDA Products will not infringe the '392 patent, thus rendering the case "exceptional," as that term is used in 35 U.S.C. § 285.

58. Unless Defendants are enjoined by the Court, Purdue Pharma and Purdue Pharmaceuticals will be substantially and irreparably harmed by Defendants' infringement of the '392 patent. Purdue Pharma and Purdue Pharmaceuticals do not have an adequate remedy at law.

FOURTH CLAIM FOR RELIEF
(PATENT INFRINGEMENT OF U.S. PATENT NO. 9,492,393)

59. Purdue Pharma and Purdue Pharmaceuticals incorporate by reference and reallege paragraphs 1 through 30 above as though fully restated herein.

60. Pursuant to 35 U.S.C. § 271(e)(2), Defendants' submission of ANDA No. 207493 to the FDA seeking approval of Defendants' ANDA Products was an act of infringement of the '393 patent by Defendants.

61. Defendants' ANDA Products, or the use thereof, are covered by one or more claims of the '393 patent, including but not limited to independent claim 1, which recites *inter alia*, a method of treating pain comprising administering to a patient in need thereof a

pharmaceutical tablet comprising at least a first compression shaped and then air cured matrix, wherein said curing is without compression by heated air having a temperature of at least about 62° C for a duration of at least about 5 minutes, said matrix comprising oxycodone or a pharmaceutically acceptable salt thereof in combination with at least one high molecular weight polyethylene oxide having, based on rheological measurements, an approximate molecular weight selected from the group consisting of 4,000,000, 7,000,000, and a combination thereof, and various claims dependent therefrom.

62. If approved by the FDA, Defendants' commercial manufacture, use, importation, sale, and/or offer for sale of Defendants' ANDA Products will infringe, contribute to the infringement of, and/or induce the infringement of one or more claims of the '393 patent under 35 U.S.C. § 271(a)-(c).

63. Defendants' ANDA Products constitute a material part of the inventions covered by the claims of the '393 patent.

64. On information and belief, Defendants know that Defendants' ANDA Products are especially made or especially adapted for use in the infringement of one or more claims of the '393 patent.

65. On information and belief, Defendants have had and continue to have knowledge that there is no substantial non-infringing use for Defendants' ANDA Products.

66. The administration of Defendants' ANDA Products by any Healthcare Providers and patients, for the treatment of pain, will directly infringe one or more claims of the '391 patent.

67. Defendants' proposed label for Defendants' ANDA Products will explicitly instruct Healthcare Providers and patients to use Defendants' ANDA Products in a

manner that will directly infringe one or more claims of the '391 patent, including but not limited to independent claim 1, which recites *inter alia*, a method of treating pain comprising administering to a patient in need thereof a pharmaceutical tablet comprising at least a first compression shaped and then air cured matrix, wherein said curing is without compression by heated air having a temperature of at least about 62° C for a duration of at least about 5 minutes, said matrix comprising oxycodone or a pharmaceutically acceptable salt thereof in combination with at least one high molecular weight polyethylene oxide having, based on rheological measurements, an approximate molecular weight selected from the group consisting of 4,000,000, 7,000,000, and a combination thereof, and various claims dependent therefrom. OxyContin® is indicated for the management of pain severe enough to require daily, around-the-clock, long-term opioid treatment and for which alternative treatment options are inadequate.

68. If Defendants' ANDA Products are approved by the FDA, Defendants will actively induce others including, *e.g.*, Healthcare Providers and patients, to directly infringe one or more claims of the '393 patent. Since at least the November 15, 2016, Defendants have acted with knowledge, or at least with willful blindness of the fact, that the induced acts would constitute infringement of the '393 patent.

69. Defendants intend to cause direct infringement by others, *e.g.*, Healthcare Providers and patients.

70. If Defendants' ANDA Products are approved by the FDA, Defendants will take affirmative steps to induce infringement by, among other things, instructing Healthcare Providers and patients, through Defendants' proposed label, to use Defendants' ANDA Products in a manner that directly infringes one or more claims of the '393 patent. Thus, Defendants will aid, abet, urge, or encourage others including, *e.g.*, Healthcare Providers and patients, to directly

infringe one or more claims of the '393 patent, and Defendants will affirmatively and specifically intend to cause direct infringement.

71. Upon information and belief, Defendants have been aware of the existence of the '393 patent, and have no reasonable basis for believing that Defendants' ANDA Products will not infringe the '391 patent, thus rendering the case "exceptional," as that term is used in 35 U.S.C. § 285.

72. Unless Defendants are enjoined by the Court, Purdue Pharma and Purdue Pharmaceuticals will be substantially and irreparably harmed by Defendants' infringement of the '393 patent. Purdue Pharma and Purdue Pharmaceuticals do not have an adequate remedy at law.

FIFTH CLAIM FOR RELIEF
(PATENT INFRINGEMENT OF U.S. PATENT NO. 9,522,919)

73. Purdue and Rhodes incorporate by reference and reallege paragraphs 1 through 30 above as though fully restated herein.

74. Pursuant to 35 U.S.C. § 271(e)(2), Defendants' submission of ANDA No. 207493 to the FDA seeking approval of Defendants' ANDA Products was an act of infringement of the '393 patent by Defendants.

75. Defendants' ANDA Products, or the use or manufacture thereof, are covered by one or more claims of the '919 patent, including but not limited to independent claims 1, 4, 12, and 18, which recite, *inter alia*, an oxycodone hydrochloride composition wherein the ratio of 8α,14-dihydroxy-7,8-dihydrocodeinone to oxycodone hydrochloride is 0.04% or less as measured by HPLC, and various claims dependent therefrom.

76. If approved by the FDA, Defendants' commercial manufacture, use, importation, sale, and/or offer for sale of Defendants' ANDA Products will infringe, contribute

to the infringement of, and/or induce the infringement of one or more claims of the '919 patent under 35 U.S.C. § 271(a)-(c).

77. Defendants' ANDA Products constitute a material part of the inventions covered by the claims of the '919 patent.

78. Upon information and belief, Defendants have been aware of the existence of the '919 patent, and have no reasonable basis for believing that Defendants' ANDA Products will not infringe the '919 patent, thus rendering the case "exceptional," as that term is used in 35 U.S.C. § 285.

79. Unless Defendants are enjoined by the Court, Purdue and Rhodes will be substantially and irreparably harmed by Defendants' infringement of the '919 patent. Purdue and Rhodes do not have an adequate remedy at law.

PRAYER FOR RELIEF

WHEREFORE, Plaintiffs pray for judgment as follows:

A. Adjudging that Defendants have infringed one or more claims of each of the '389, '391, '392, '393, and '919 patents, and that the commercial sale, offer for sale, use, importation, and/or manufacture of Defendants' ANDA Products would infringe, induce infringement of, and/or contribute to the infringement of one or more claims of each of the '389, '391, '392, '393, and '919 patents;

B. Adjudging, pursuant to 35 U.S.C. § 271(e)(4)(A), the effective date of any approval of ANDA No. 207493 and Defendants' ANDA Products, under § 505(j) of the Federal Food, Drug and Cosmetic Act (21 U.S.C. § 355(j)), to be a date not earlier than the last date of expiration of the '389, '391, '392, '393, and '919 patents, plus any additional periods of extension or exclusivity attached thereto;

C. Preliminarily and permanently enjoining, pursuant to 35 U.S.C. §§ 271(e)(4)(B) and 283 and Rule 65, Fed. R. Civ. P., Defendants, their officers, partners, agents, servants, employees, parents, subsidiaries, divisions, affiliate corporations, other related business entities, and all other persons acting in concert, participation, or in privity with them, and their successors and assigns, from any commercial manufacture, use, offer to sell, or sale within the United States, or importation into the United States, of any drug product that is the subject of ANDA No. 207493, including Defendants' ANDA Products or any other drug product that infringes the '389, '391, '392, '393, and '919 patents;

D. Declaring this an exceptional case and awarding Plaintiffs their attorneys' fees and costs, as provided by 35 U.S.C. §§ 271(e)(4) and 285; and

E. Awarding Plaintiffs such other and further relief as this Court may deem just and proper.

MORRIS, NICHOLS, ARSHT & TUNNELL LLP

/s/ Rodger D. Smith II

Jack B. Blumenfeld (#1014)
Rodger D. Smith II (#3778)
1201 North Market Street
P.O. Box 1347
Wilmington, DE 19899
(302) 658-9200
jblumenfeld@mnat.com
rsmith@mnat.com

Attorneys for Plaintiffs

OF COUNSEL:

John J. Normile
Pablo D. Hendler
Kelsey I. Nix
Gasper J. LaRosa
Kenneth S. Canfield
Sarah A. Geers
Lisamarie LoGiudice
JONES DAY
250 Vesey Street
New York, NY 10281-1047
(212) 326-3777

Jason G. Winchester
JONES DAY
77 West Wacker Drive
Chicago, IL 60601

April 20, 2017